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The Center for  
Reproductive Medicine

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December 21, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5360 Fishers Lane  
Room 1060  
Rockville, Maryland 20852

Re: Docket #97N-484S

Suitability determination for donors of human cellular and tissue based  
products

Dear Food and Drug Administration:

I am corresponding with you regarding your objectionable and totally unacceptable proposed rule regarding the requirement to test an egg donor before the donor egg IVF cycle, freeze the resultant embryo and then quarantine these embryos until 6 months later when the donor is re-tested for infectious disease. The above statement clearly demonstrates your lack of understanding of this sensitive area of assisted reproductive technology. The logic regarding the above recommendation is markedly flawed for a number of reasons. A few examples are listed below:

- 1) There is no evidence that oocytes, embryos or isolated sperm cells used in IVF are vectors of the diseases listed in the FDA proposal. No HIV has been contracted from IVF in 21 years. If you know of a case, please share it with me and with SART.
- 2) Quarantining embryos will significantly increase cost and will decrease the number of cycles to obtain the same pregnancy rate. It is our estimate that in our practice the cost would increase by at least 2-3 fold. These procedures are extremely expensive to begin with.

97N 484S

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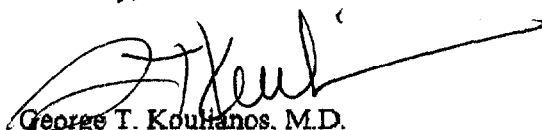
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- 3) Quarantining embryos will decrease the success rate for donor IVF by about half. Again, increasing the number of cycles and cost for patients.
- 4) Freezing and thawing embryos will result in un-necessary embryo death and represents a terrible and wasteful loss of biologic material.
- 5) There is no way to measure the anxiety caused by this delay in our patients waiting to receive these donated embryos. Human oocytes need to be treated differently than frozen sperm. The risks and hazards are different for each tissue. Also, donor oocytes are much more limited compared to the tens of millions of sperm that one would obtain with an ejaculate.

Again, I thank you for your assistance in this matter and hope that you will act in the best interest of the patients we all serve.

Sincerely,

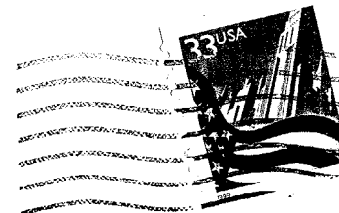


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